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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/637,752	07/20/2001	Andrea Kern	8484010999	4876

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EXAMINER
MOSHER, MARY

ART UNIT	PAPER NUMBER
1648	23

DATE MAILED: 04/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/637,752	Kern et al
Examiner	**Art Unit**
Mosher	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *11/30/01* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *12, 13, and 16-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *12, 13, and 16-21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

The substitute specification filed 12/15/2001 has been approved for entry.

Election/Restriction

Applicant's election without traverse of group II, antibody products, in Paper No. 16 is acknowledged. All nonelected claims have been canceled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16 and 17 are rejected under 35 U.S.C. 101 because they encompass nonstatutory products of nature. This rejection could be obviated by inserting language such as "isolated", to exclude antibodies as they exist in the body as made in response to natural infection.

Claim Rejections - 35 USC § 112

Claims 12, 13, and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There are two aspects of this rejection, one relating to making the specific named monoclonal antibodies, and one relating to use of the claimed kit.

It is apparent that the monoclonal antibodies recited in claims 13 and 18-21 are required to practice the claimed invention. As required elements they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit. It is noted that a deposit has been made; however, the deposit statement (on page 3 of the substitute specification) does not state the terms of the deposit or the extent of public availability.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

In regard to claims 12-13, the claim preamble states "A kit for detecting the causative agent of spontaneous abortion..." Therefore, in order to use the claimed kit, it must be able to detect the causative agent of spontaneous abortion. The specification teaches detection of AAV DNA in biopsy material by Southern blot or PCR amplification, and teaches detection of anti-AAV antibodies in the maternal serum. The specification also teaches an immunoassay for detecting AAV using the A20 antibody, and teaches a standard curve with a lower range of 10 capsids/ml using purified materials. However, the specification does not contain any working examples of detecting AAV antigen in spontaneous abortion material. There are no teachings regarding the quantity of AAV antigen present in spontaneous abortion material, nor the sensitivity of the antibodies for detecting AAV, nor the specificity of the antibodies when presented with the complex mixture of biological materials present in biopsy samples. Therefore, one skilled in the immunoassay art would have reason to doubt unsupported assertions that a probe antibody, such as applicant's monoclonal antibodies, will detect AAV antigen in material from spontaneous abortions. Considering the limited teachings in the specification and the lack of working examples, it is concluded that undue experimentation would be required to use the kit in the manner required by the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 17 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Ruffing et al (AK). See page 6924, "Preparation of anti-VP3 serum."

Claims 16 and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hunter et al, Hoggan et al, or Georg-Fries et al. See for example: in Hunter et al, the Abstract, Figure 8, and page 321, second column ("Colocalization of AAV rep and capsid proteins in AAV-infected cells"); in Hoggan et al, page 1468 ("Preparation of antiserum"); in Georg-Fires et al, page 65 ("Monoclonal antibodies," "Immunoprecipitation").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruffing et al (AK) or Hunter et al or Hoggan et al or Georg-Fries et al. Claim 12 is directed to a kit comprising an antibody directed to an AAV antigen in a suitable container. Each of the references teaches an anti-AAV antibody, but does not explicitly state that the antibody is in a container. Since it is conventional to place proteins such as antibodies in containers, it would have been very obvious to place the antibodies in a container for handling and storage, thereby meeting the claim's requirements. Therefore the invention as a whole is prima facie obvious. It is noted that the references do not suggest the intended use "for detecting the causative agent of spontaneous abortion;" however this statement of intended use in the claim preamble does not place any definite limitations upon the contents of the kit.

Claims 13 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Georg-Fries et al and Ruffing et al. Georg-Fries et al teaches monoclonal antibodies made against AAV type 5 capsids, and their use to specifically detect AAV-5, see for example Figure 2. These monoclonal antibodies differ from the claimed monoclonal antibodies in that the claimed monoclonal antibodies appear to be directed against AAV type 2, not type 5. However Ruffing et al teaches polyclonal antibodies directed against AAV type 2 capsid proteins. It would have been within the ordinary skill of the art to make monoclonal antibodies, similar to those made by Georg-Fries et al, but directed against the type 2 capsid proteins, for the purposes of a convenient

and reproducible source of type-2 specific reagents. The invention as a whole is therefore prima facie obvious, absent unexpected results.

The following references are cited as of interest, as related to AAV infection during pregnancy in mice, and in human infants: Lipps et al and Dreizin et al. Shimada et al (6,093,534, not available as prior art) is also cited as of interest in claiming specific anti-AAV-CAP monoclonal antibodies.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 14, 2003

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1400